International Standard

ISO/IEEE 11073-10421

Second edition
2024-08

Health informatics — Device interoperability —

Part 10421: Personal health device communication — Device specialization — Peak expiratory flow monitor (peak flow)

Informatique de santé — Interopérabilité des dispositifs —Partie 10421: Communication entre dispositifs de santé personnels — Spécialisation des dispositifs — Moniteur de surveillance du débit expiratoire de pointe (débit de pointe)

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This second edition cancels and replaces the first edition (ISO/IEEE 11073-10421:2012), which has been technically revised.

The main changes are as follows:

— added support for Base-Offset-Time;

— defined new standard configuration 0x0835;

— updated normative references, to refer to ISO/IEEE 11703-20601;

— updated version of this device specialization;

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— updated the association details based on the new version;

— updated the wording in 6.3 regarding the Observational;

— updated the examples in 8.4.2 and Annex E to indicate the support of BaseOffsetTime;

— updated the qualifier in MDS and other objects to recommend BaseOffsetTime; also updated the description of the qualifiers in 6.5;

— added some text to 6.12 to further elaborate the DIM extensibility rule;

— corrected the use condition of GET MDS at E.4.1;

— updated the text in 8.5.2 regarding attribute-id-list, in order to be compliant with 20601-V4;

— added subclause 3.4 – Compliance with other standards;

— removed the year in the bibliography to represent the latest version;

— extended Table 1 to specify qualifier details for all possible configurations;

— made the IEEE std 11073-10101 as normative reference;

— updated the wording at 1.3 and 4.1 regarding the precedence of nomenclature between 10101, 20601, 104xx, and this standard;

— updated the usage of nomenclature-version. Tied it with the corresponding protocol-version.

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IEEE Std 11073-10421™-2023
(Revision of IEEE Std 11073-10421-2010)

Health Informatics—Device Interoperability

Part 10421: Personal Health Device Communication—Device Specialization—Peak Expiratory Flow Monitor (Peak Flow)

Developed by the

IEEE 11073™ Standards Committee
of the
IEEE Engineering in Medicine and Biology Society

Approved 30 March 2023

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Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, a normative definition of communication is established in this standard between personal telehealth peak expiratory flow monitor devices and compute engines (e.g., cell phones, personal computers, personal health appliances, and set-top boxes) in a manner that enables plug-and-play interoperability. Appropriate portions of existing standards are leveraged, including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards. The use of specific term codes, formats, and behaviors is specified in telehealth environments restricting optionality in base frameworks in favor of interoperability. A common core of communication functionality is defined for personal telehealth peak expiratory flow monitor devices.

Keywords: forced expiratory volume, IEEE 11073-10421™, medical device communication, peak expiratory flow, peak expiratory flow monitor, peak flow, personal health devices

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This introduction is not part of IEEE Std 11073-10421™-2023, Health Informatics—Device Interoperability—Part 10421: Personal Health Device Communication—Device Specialization—Peak Expiratory Flow Monitor (Peak Flow).

The object classes and attributes in this standard are identified by nomenclature codes. Each code consists of a reference identifier (RefID) string and an integer code value. By using a consistent nomenclature, interoperability is enhanced as all implementations maintain the same semantic meaning for the numeric codes. This standard leverages the existing nomenclature codes in IEEE Std 11073-10101™. Between this standard, IEEE Std 11073-10101, ISO/IEEE 11073-20601, and other IEEE Std 11073-104zz, all required nomenclature codes for implementation are documented. New codes may be defined in newer versions/revisions of each of these documents. In the case of a conflict, where one term code has been assigned to two separate semantic concepts with different RefIDs, in general, the oldest definition in actual use should take precedence. The same policy applies when one RefID has two different code values assigned in different specifications. The resolution of such conflicts will be determined through joint action by the responsible working groups and other stakeholders, and any corrective action will be published as corrigenda.

NOTE—In this standard, IEEE 11073-104zz is used to refer to the collection of device specialization standards that utilize ISO/IEEE 11073-20601, where zz can be any number from 01 to 99, inclusive.[6]

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Health Informatics—Device Interoperability

Part 10421: Personal Health Device Communication—Device Specialization—Peak Expiratory Flow Monitor (Peak Flow)

1. Overview

1.1 Scope

The scope of this standard is to establish a normative definition of communication between personal telehealth peak flow monitoring devices (agents) and managers (e.g., cell phones, personal computers, personal health appliances, and set top boxes) in a manner that enables plug-and-play interoperability. It leverages work done in other ISO/IEEE 11073 standards including existing terminology, information profiles, application profile standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability. This standard defines a common core of functionality of a peak-flow monitoring device. The use case is restricted to personal respiratory monitoring and therefore does not include hospital-based spirometry. Continuous and high-acuity monitoring (e.g., for emergency response) are outside the scope of the use case. In the context of personal health devices, a peak flow meter is a device used to measure the respiratory function of those managing respiratory conditions such as asthma and chronic obstructive pulmonary disease. The ability to identify declining respiratory status prior to the need for acute intervention improves the quality of life for the individual while reducing the overall costs of care. Respiratory status data are collected by a personal respiratory monitoring device and forwarded to a central data repository for review and action by a health care provider. The data are episodic in nature and are forwarded at designated intervals or when the person is symptomatic.

1.2 Purpose

This standard addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices and managers (e.g., cell phones, personal computers, personal health appliances, and set top boxes). Interoperability is key to growing the potential market for these devices and enabling people to be better informed participants in the management of their health.

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1.3 Word usage

The word *shall* indicates mandatory requirements strictly to be followed in order to conform to the standard and from which no deviation is permitted (*shall* equals *is required to*).[7,8]

The word *should* indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others; or that a certain course of action is preferred but not necessarily required (*should* equals *is recommended that*).

The word *may* is used to indicate a course of action permissible within the limits of the standard (*may* equals *is permitted to*).

The word *can* is used for statements of possibility and capability, whether material, physical, or causal (*can* equals *is able to*).

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used, so each referenced document is cited in the text and its relationship to this document is explained). For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments or corrigenda) applies.

ISO/IEEE 11073-10101, Health informatics—Device interoperability—Part 10101: Point-of-care medical device communication—Nomenclature.[9,10]

ISO/IEEE 11073-20601, Health informatics—Device interoperability—Part 20601: Personal health device communication—Application profile—Optimized exchange protocol.

See Annex A for all informative material referenced by this standard.

3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this document, the following terms and definitions apply. The *IEEE Standards Dictionary Online* should be consulted for terms not defined in this clause. [11]

agent: A node that collects and transmits personal health data to an associated manager.

class: In object-oriented modeling, a class describes the attributes, methods, and events that objects instantiate from the class utilize.

compute engine: *See:* **manager.**

[7] The use of the word *must* is deprecated and cannot be used when stating mandatory requirements; *must* is used only to describe unavoidable situations.
[8] The use of *will* is deprecated and cannot be used when stating mandatory requirements; *will* is only used in statements of fact.
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device: A term used to refer to a physical apparatus implementing either an agent or a manager role.

forced expiratory volume: The expiratory volume of a subject under forced conditions at time t in seconds, measured from time zero.

handle: An unsigned 16-bit number that is locally unique and identifies one of the object instances within an agent.

manager: A node receiving data from one or more agent systems. Some examples of managers include a cellular phone, health appliance, set top box, or a computer system.

obj-handle: *See:* **handle.**

object: In object-oriented modeling, a particular instantiation of a class. The instantiation realizes attributes, methods, and events from the class.

peak expiratory flow: maximum flow measured at the mouth during an expiration delivered with maximal force starting immediately after achieving maximum lung inflation.

peak expiratory flow monitor: A medical device used to measure the respiratory function of those managing respiratory conditions such as asthma.

personal best: This value is determined by a healthcare professional or based on predicted average peak flow and is typically the highest peak expiratory flow (PEF) reading an individual can obtain while in peak condition.

personal health device: A device used in personal health applications.

personal telehealth device: *See:* **personal health device.**

predicted average peak flow: The value of peak expiratory flow that is calculated based on the user's age, height, and sex to serve as a benchmark for the user's measurements.

time zero: In the context of this document, time zero is the instant at which a user starts blowing into the peak-flow monitor to record a measurement.

3.2 Acronyms and abbreviations

APDU	application protocol data unit
ASN.1	Abstract Syntax Notation One
DIM	domain information model
EUI-64	extended unique identifier (64 bits)
FEV	forced expiratory volume
FEV1	forced expiratory volume in 1 s
FEV6	forced expiratory volume in 6 s
ICS	implementation conformance statements

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MDC	medical device communication
MDER	medical device encoding rules
MDS	medical device system
MOC	managed object class
OID	object identified
PDU	protocol data unit
PEF	peak expiratory flow
PHD	personal health device
VMO	virtual medical object
VMS	virtual medical system

4. Introduction to ISO/IEEE 11073 personal health devices

4.1 General

This standard and the remainder of the series of ISO/IEEE 11073 personal health device (PHD) standards fit in the larger context of the ISO/IEEE 11073 series of standards. The full suite of standards enables agents to interconnect and interoperate with managers and with computerized health-care information systems. See ISO/IEEE 11073-20601 for a description of the guiding principles for this series of ISO/IEEE 11073 Personal Health Device standards.

ISO/IEEE 11073-20601 supports the modeling and implementation of an extensive set of personal health devices. This standard defines aspects of the peak expiratory flow monitor device. It describes all aspects necessary to implement the application layer services and data exchange protocol between an ISO/IEEE 11073 PHD peak expiratory flow monitor agent and a manager. This standard defines a subset of the objects and functionality contained in ISO/IEEE 11073-20601 and extends and adds definitions where appropriate. All new definitions are given in Annex B in Abstract Syntax Notation One (ASN.1) [B8]. Nomenclature codes referenced in this standard, which are not defined in ISO/IEEE 11073-20601, are normatively defined in Annex C.

4.2 Introduction to IEEE 11073-20601 modeling constructs

4.2.1 General

The ISO/IEEE 11073 series of standards, and in particular ISO/IEEE 11073-20601, is based on an object-oriented systems management paradigm. The overall system model is divided into three principal components: the domain information model (DIM), the service model, and the communication model. See ISO/IEEE 11073-20601 for a detailed description of the modeling constructs.

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4.2.2 Domain information model

The DIM is a hierarchical model that describes an agent as a set of objects. These objects and their attributes represent the elements that control behavior and report on the status of the agent and data that an agent can communicate to a manager. Communication between the agent and the manager is defined by the application protocol in ISO/IEEE 11073-20601.

4.2.3 Service model

The service model defines the conceptual mechanisms for the data exchange services. Such services are mapped to messages that are exchanged between the agent and the manager. Protocol messages within the ISO/IEEE 11073 series of standards are defined in ASN.1. The messages defined in ISO/IEEE 11073-20601 can coexist with messages defined in other standard application profiles defined in the ISO/IEEE 11073 series of standards.

4.2.4 Communication model

In general, the communication model supports the topology of one or more agents communicating over logical point-to-point connections to a single manager. For each logical point-to-point connection, the dynamic system behavior is defined by a connection state machine as specified in ISO/IEEE 11073-20601. The security of this communication is largely determined by, but not limited to, the physical security of the device along with the inherent security of the underlying transports. Additional security may be defined by future revisions of ISO/IEEE 11073-20601.

4.2.5 Implementing the models

An agent implementing this standard shall implement all mandatory elements of the information, service, and communication models as well as all conditional elements where the condition is met. The agent should implement the recommended elements, and it may implement any combination of the optional elements. A manager implementing this standard shall utilize at least one of the mandatory, conditional, recommended, or optional elements. In this context, “utilize” means to use the element as part of the primary function of the manager device. For example, a manager whose primary function is to display data would need to display a piece of data in the element in order to utilize it.

4.3 Compliance with other standards

Devices that comply with this standard may also be required to comply with other domain- and device-specific standards that supersede the requirements of this standard with respect to issues including safety, reliability, and risk management. A user of this standard is expected to be familiar with all other such standards that apply and to comply with any higher specifications thus imposed.

Typically, medical devices should comply with the IEC 60601-1 [B1] base standards with respect to electrical and mechanical safety and any device-specific standard as might be defined in the IEC 60601-2 [B2] series of standards. Software aspects may apply through standards such as IEC 62304 [B3]. Devices that comply with this standard implement higher layers of network software and utilize lower layers as appropriate to the application. The requirements for the performance of such applications and conformance are defined elsewhere and are outside the scope of this standard. Moreover, the use of any medical equipment is subject to risk assessment and risk management appropriate to the application. Some relevant examples are ISO 14971 [B5] and IEC 80001-1 [B4]. The requirements of such risk assessment, risk management, and conformance are outside the scope of this standard. The applicable versions of the referenced safety-related standards may differ per country.

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5. Peak expiratory flow monitor device concepts and modalities

5.1 General

This clause presents the general concepts of peak expiratory flow monitor devices. In the context of personal health devices in this family of standards, a peak expiratory flow monitor is a device that measures the respiratory function of those managing respiratory conditions such as asthma. In general, the peak expiratory flow monitor will take measurements of the lung function of the subject by recording the flow and volume of air during exhalation with maximum effort. Typically, a peak expiratory flow monitor accomplishes this task by measuring and recording peak expiratory flow (PEF) and forced expiratory volume in 1 s (FEV1). In some cases, forced expiratory volume in 6 s (FEV6) is also measured.

The methods to determine PEF and forced expiratory volume (FEV) vary, but common methods include the use of pressure sensors, mechanical turbines, piezo-electric crystals, and so on as sensors. The subject is required to deliver an expiration with maximal force into a mouthpiece that channels the air to the sensor. Typically, the sensor will measure airflow to determine PEF, and from the area of the tube in which the sensor is placed, the volume (FEV1 or FEV6) may be calculated.

5.2 PEF

PEF is a measure of how fast an individual can push air out of their lungs after taking maximal inspiration and followed by a maximal expiration. PEF is measured in liters per minute. Figure 1 shows the typical rate of flow during the measurement of PEF with the maximal value at around 0.1 s.

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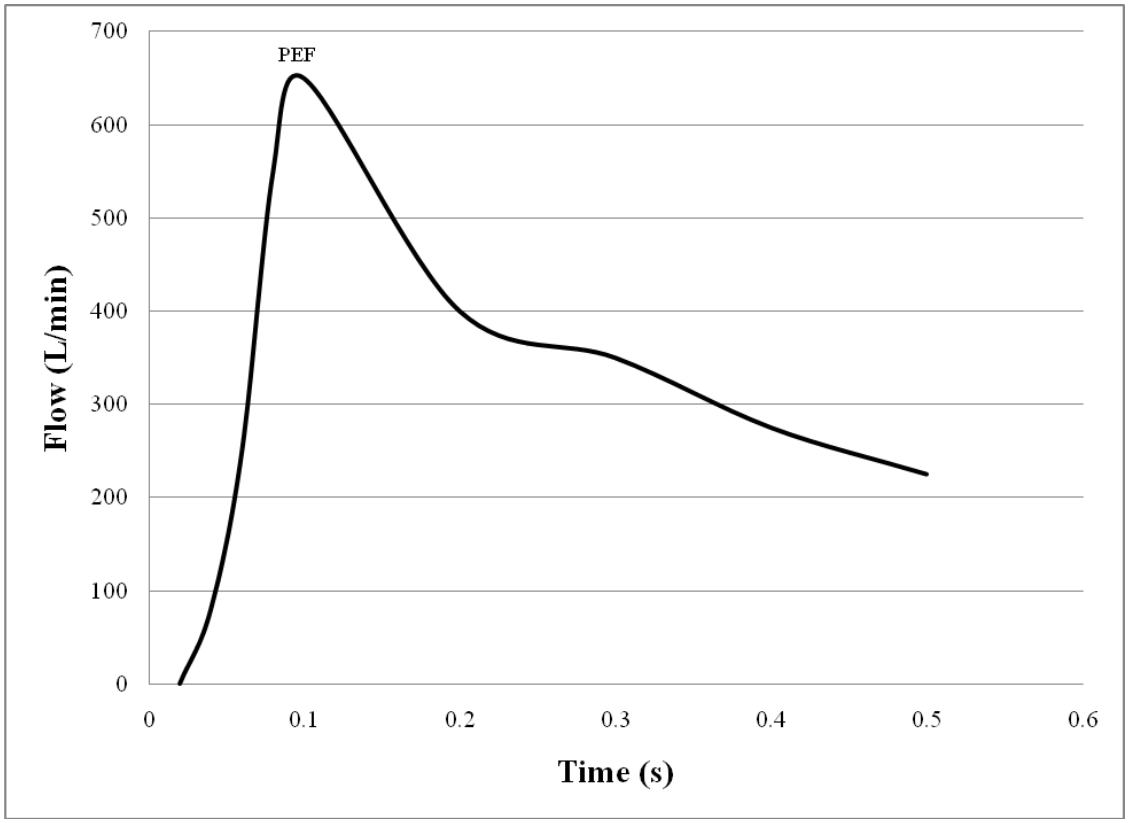

Figure 1—PEF waveform (representation only—does not correspond to real values)

5.3 Personal best

Personal best is not a constantly measured value; rather, it is determined by a health-care professional or based on predicted average peak flow. The personal best is typically the highest PEF reading an individual can obtain while in peak condition. Personal best, as a value of PEF, is measured in liters per minute.

5.4 FEV1

FEV1 is a measure of forced expiratory volume. It is a measure of the expiratory volume of a subject under forced conditions at 1 s, measured from time zero (the time at which the subject starts the expiration). FEV1 is measured in liters. Figure 2 shows a typical pulmonary waveform where FEV1 is the total volume of air and would be calculated as the area under the curve between 0 s and 1 s.

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